

## II. REMARKS

### Preliminary Remarks

This amendment and response is timely filed as it is accompanied by a petition for an extension of time to file in the first month and the requisite fee. As a convenience to the examiner, the claims, as marked per the foregoing amendment, are set forth in an appendix attached hereto.

Support for new claims 13-30 is found throughout the specification and claims as originally filed. No new matter is believed to have been introduced by the foregoing amendment.

### Defective Oath/Declaration

The examiner asserted that the inventor oath/declaration is defective in that non-initialized and/or non-dated alterations have been made to said document. In response, the applicants submit herewith a properly executed oath/declaration that does not contain the defects referred to by the examiner. The applicants request that acknowledgement that the applicants have submitted a properly executed oath/declaration.

### Drawings

The applicants have noted the objections to the drawings. Formalization of the drawings will be attended to after a notice of allowability has been received.

### Objection/Specification

The examiner objected to the specification at page 5, lines 6-9 by stating that the sentence is unclear and appears to be missing something. In response, the applicants request withdrawal of the objection in that by the foregoing amendment to the specification, the

applicants have amend that portion of the specification to more clear define the applicants' invention.

#### Objection/Claims

The examiner objected to claim 5 in that the language of the claim should read as "contains at least" rather than "contain at least." The applicants submit that this objection is now moot as such language has been removed from the claim. Therefore, the applicants request withdrawal of this claim objection.

#### Rejections Based Upon 35 U.S.C. 112, Second Paragraph

The examiner rejected claims 2-6 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Specifically, the examiner asserted that claims 2-5 were unclear with respect to use of the language "composite plasmid." As suggested by the examiner, the applicants have amended the claims to refer to "plasmids."

The examiner asserted that claim 6 was allegedly indefinite with respect to use of the language "at least one active substance resistance one of the plasmids pTET3..." In response, the applicants have amended claim 6 to refer to a "resistance region."

With respect to claims 2-6, the examiner asserted that use of the language "active substance resistance" was allegedly indefinite. The applicants submit that this rejection is now moot in that the claims now refer to "antibiotic resistance."

The examiner, with respect to claim 2, alleged that use of the language "derived from" is unclear. The applicants have replaced the language referred to by the examiner with "obtained," to more clearly define the applicants' claimed invention.

In view of the foregoing, the applicants submit that as amended herein the claims are neither vague nor indefinite and therefore respectfully request that the rejections based upon 35 U.S.C. §112, second paragraph be withdrawn.

Rejections Based Upon 35 U.S.C. §112, First Paragraph

Claims 2-6 were rejected under 35 U.S.C. §112, first paragraph as allegedly being broader than the enabling disclosure. The examiner contends that the claims embrace all possible plasmids capable of replication in coryneform bacteria and having the claimed characteristics. The examiner indicates that the specification only provides representative species isolated from *Corynebacterium glutamicum*.

In response the applicants submit that claims 2-6 are fully enabled by the specification. Specifically, the applicants submit that the applicants' claims, as amended herein, are directed to a finite number of plasmids that are capable of autonomous replication in bacteria of the genus *corynebacterium*, wherein the plasmid comprises: i) at least a portion of the nucleotide sequence of plasmid pTET3 or pCRY4; ii) at least one DNA replication region obtained from one of the plasmids pTET3 or pCRY4; and iii) at least one region that encodes a protein for active antibiotic resistance. Clearly, the defined plasmid is fully supported and enabled by the present specification

Claims 2-7 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking support from an enabling specification. Specifically, because the application does not set forth how to synthesize the inventive plasmids, it is allegedly not clear that the sequences required to construct these plasmids are readily available to the public. In response, the applicants submit herewith a duly executed declaration of biological deposit (executed by the undersigned) with respect to the novel plasmids disclosed in the present specification.

Rejections Based Upon 35 U.S.C. §§102(a) and (b)

Claims 2 and 5 were rejected under 35 U.S.C. § 102(b) as being anticipated by a 1998 article authored by Zhang *et al.* (claim 2) or under 35 U.S.C. §102(a) as being anticipated by a 1999 article authored by Guillouet *et al.* (claims 2 and 5).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The applicants submit that neither of the documents cited by the examiner require "at least on DNA replication region obtained from one of the plasmids pTET3 or pCRY4," as amended herein. In view of this difference, neither cited document may properly anticipate the claimed invention.

In view of the foregoing, the applicants request that the rejections based upon 35 U.S.C. §102(a) and 35 U.S.C. §102(b) be withdrawn.

### III. CONCLUSION

In view of the foregoing, the claims are now believed to be in form for allowance, and such action is hereby solicited. If any point remains in issue that the examiner feels may be best resolved through a personal or telephone interview, the examiner is strongly urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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Enclosure: Appendix  
Declaration of Biological Deposit

APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

The paragraph at page 5, lines 6-9 of the specification was amended as follows.

The present invention also provides novel composite plasmids [which] that contain at least part of [the] an active substance [resistance(s)] resistance region [and pGA1 and/or pGA2 from the novel plasmids according to the invention].

IN THE CLAIMS

Claims 4, 7 and 8 were deleted.

The claims were amended as follows:

2. (Amended) A [composite] plasmid capable of autonomous replication in [coryneform] bacteria of the genus Corynebacterium, said plasmid comprising:
- i) at least a portion of the nucleotide sequence of plasmid pTET3 or pCRY4,
  - ii) at least one DNA replication region [derived] obtained from one of the plasmids pTET3 or pCRY4, and
  - iii) [a gene fragment which is derived from *E. coli*, *B. subtilis* or *Streptomyces* and may multiply therein, and]
  - [iv)] at least one region that [expresses] encodes a protein for active [substance] antibiotic resistance.
3. (Amended) [A composite] The plasmid [according to] of claim 2, [which contains at least one region for active substance resistance from plasmid pTET3] wherein said region that encodes a protein for antibiotic resistance comprises a gene selected from the group consisting of: a gene encoding a protein conferring tetracycline resistance, a gene encoding a protein conferring streptomycin and spectinomycin resistance and a gene conferring sulfamethoxazole resistance, wherein said genes are obtained from the antibiotic resistance region of plasmid pTET3, as set forth in Figure 5.
5. (Amended) [A composite] The plasmid [according to] of claim 2, [which contain] wherein said plasmid comprises at least one DNA fragment [which encodes a gene from the biosynthetic pathway of a vitamin, a nucleotide or an L-amino acid

and is expressed in coryneform bacteria] selected from the group consisting of: a DNA fragment encoding a protein from the biosynthetic pathway of a vitamin, a DNA fragment encoding a protein from the biosynthetic pathway of a nucleotide and a DNA fragment encoding a protein from the biosynthetic pathway of an L-amino acid.

6. (Amended) A plasmid [vector] capable of autonomous replication in [coryneform] bacteria of the genus Corynebacterium containing:

- i) at least one DNA replication region [derived] obtained from one of the plasmids pGA1, pGA2, pTET3 or pCRY4, and
- ii) at least one [active substance] antibiotic resistance gene obtained from the antibiotic resistance region of plasmid pTET3 [and optionally] shown in Figure 5.
- [iii) at least one DNA fragment which encodes a gene from the biosynthetic pathway of a vitamin, a nucleotide or an L-amino acid and is expressed in coryneform bacteria.]

Claims 13-32 were added

End of Appendix